SEP 21 2000

K002878

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Summary of Safety and Effectiveness

September 13, 2000

Subject:	510(k) Summary of Safety and Effectiveness Information for the Datex-Ohmeda D-Tec Plus Anesthesia Vaporizer
Proprietary:	Datex-Ohmeda D-Tec Plus Anesthesia Vaporizer
Common:	Vaporizer, Anesthesia
Classification:	Anesthesiology, 73CAD, 21CFR868.5880

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 1992.

The Datex-Ohmeda D-Tec Plus anesthesia vaporizer is substantially equivalent to the following currently marketed device:

1. Ohmeda Tec 6 vaporizer - Class II - 21CFR868.5880 73CAD
2. Ohmeda Tec vaporizer - NAD variant - Class II - CFR868.5880 73CAD
3. Datex-Ohmeda Tec 6 Plus (Datex-Ohmeda and NAD Variants) vaporizer - Class II - CFR868.5880 73CAD
4. Datex-Ohmeda D-Tec vaporizer - Class II - CFR868.5880 73CAD

The Datex-Ohmeda D-Tec Plus anesthesia vaporizer is device that delivers physician selected concentrations of desflurane anesthetic agent to a flow of medical gases through an anesthesia machine, and to the patient. The spacing of the port valves, helps ensure that the Datex-Ohmeda D-Tec Plus anesthesia vaporizer can only be mounted on Dragerwerk anesthesia systems with a Dragerwerk interlocking manifold.

The Datex-Ohmeda D-Tec Plus anesthesia vaporizer was designed to comply with the applicable portions of the following voluntary standards;

1. EN 740 - Anesthetic Work Stations
2. EN 60601-1, IEC 601-1: 1988 - Medical Electrical Equipment
3. EN 60601-1-2, IEC 601-1-2: 1998 - Medical Electrical Equipment – Electromagnetic Compatability
4. ISO 5358 - Anesthetic Gas Machines
5. ASTM F1161 - Specifications for Anesthetic Gas Machines

The Datex-Ohmeda D-Tec Plus anesthesia vaporizer and the currently marketed devices are substantially equivalent in design concepts, technologies and materials. The Datex-Ohmeda D-Tec Plus anesthesia vaporizer has been validated through rigorous testing that, in part, support the compliance of the Datex-Ohmeda D-Tec anesthesia vaporizer to the above mentioned standards.

Datex·Ohmeda

Datex-Ohmeda D-Tec Plus Anesthesia Vaporizer

Device Name - Proprietary, Common and Classification

Device Name - Proprietary:	Datex-Ohmeda D-Tec Plus
Device Name - Common:	Vaporizer, Anesthesia
Device Name - Classification:	73CAD - Class II - 21CFR868.5880

Device Classification and Panel

Device Classification:	73CAD - Class II - 21CFR868.5880
Device Panel:	Anesthesiology

Performance Standards Information

To the best of Datex-Ohmeda's knowledge, performance standards have not been promulgated by FDA for this device.

Manufacturing Facility Information

Datex-Ohmeda, Inc.
Anesthesia, Drug Delivery and Ventilation Business Unit
Ohmeda Drive - PO Box 7550
Madison, WI 53707-7550
(608) 221-1551 telephone
(608) 223-2496 facsimile

Establishment Registration and Owner/Operator Numbers

Establishment Registration Number:	2112667
Owner/Operator Number:	8030853

Predicate Devices for the Datex-Ohmeda D-Tec Plus Anesthesia Vaporizer

Ohmeda Tec 6 Anesthesia Vaporizer	K913593C
Ohmeda Tec 6 NAD Variant Anesthesia Vaporizer	K925580A
Datex-Ohmeda Tec 6 Plus and Tec 6 Plus NAD Variant Anesthesia Vaporizer	K000275
Datex-Ohmeda D-Tec Anesthesia Vaporizer	K990132

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 21 2000

Mr. Daniel Kosednar
Datex-Ohmeda
Ohmeda Drive
P.O. Box 7550
Madison, WI 53707-7550

Re: K002878
Datex-Ohmeda D-Tec Plus Anesthesia Vaporizer
Regulatory Class: II (two)
Product Code: 73 CAD
Dated: September 13, 2000
Received: September 15, 2000

Dear Mr. Kosednar:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K

Device Name: Datex-Ohmeda D-Tec Plus Anesthesia Vaporizer

Indications For Use:

The Datex-Ohmeda D-Tec Plus is an electronic vaporizer which delivers the anesthetic agent desflurane. The D-Tec Plus attaches to the Dragerwerk interlocking manifold.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number: K00 2578

Prescription Use ✓ OR Over-The-Counter Use
(Per 21CFR801.109) (Optional Format 1-2-96)